DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: DUREZOL
Docket No.: FDA-2009-E-0021

JUL 15 2009

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,114,319, filed by Senju Pharmaceutical Co. Ltd, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for DUREZOL (difluprednate ophthalmic emulsion), the human drug product claimed by the patent.

The total length of the regulatory review period for DUREZOL (difluprednate ophthalmic emulsion) is 560 days. Of this time, 379 days occurred during the testing phase and 181 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: December 13, 2006.

   FDA has verified the applicant's claim that the investigational new drug application became effective on December 13, 2006.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 26, 2007.

   FDA has verified the applicant's claim that the new drug application (NDA) 22-212 was submitted on December 26, 2007.

3. The date the application was approved: June 23, 2008.

   FDA has verified the applicant's claim that NDA 22-212 was approved on June 23, 2008.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Warren M. Cheek, Jr.
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